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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,805	02/12/2004	Scott L. Diamond	53893-5043	5374

23973 7590 08/24/2006

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/777,805	DIAMOND ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D.	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-18 in full and 22-26 in part, drawn to methods of making a cationic nonviral delivery vehicle by mixing together a steroid, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid, classified in class 514, subclass 171.
2. Claims 22-26, in part, drawn to methods of making a cationic nonviral delivery vehicle by mixing together a non-steroid drug, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the non-steroid drug or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid, classified in class 514, subclass 1.
3. Claims 19-21, and 52, in full and 27-29 and 53 in part, drawn to a cationic nonviral delivery vehicle, made by mixing together a steroid, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid, classified for example in class 424, subclass 450.

4. Claims 27, 29 and 53, in part, drawn to a cationic nonviral delivery vehicle, made by mixing together a non-steroid drug, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid, classified for example in class 424, subclass 450.

5. Claims 30, 32-34, 38-47, and 54, in full and claims 31, 35-37, and 55 in part, drawn to methods of facilitating delivery of a compound to a cell or tissue comprising administering to the cell or tissue a composition comprising the compound and an effective amount of a cationic delivery vehicle made by mixing together a steroid, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid, classified for example in class 435, subclass 458.

6. Claims 31, 35-37, and 55, in part, drawn to methods of facilitating delivery of a compound to a cell or tissue comprising administering to the cell or tissue a composition comprising the compound and an effective amount of a cationic delivery vehicle made by mixing together a non-steroid drug, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or

modification or derivative thereof, purifying the conjugate, and mixing it with a lipid, classified for example in class 435, subclass 458.

7. Claims 48-50 in full, and claim 51 in part, drawn to methods of treating a disease or disorder in a mammal comprising administering to the mammal or tissue a composition comprising the compound and an effective amount of a cationic delivery vehicle, made by mixing together a steroid, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid classified for example in class 514, subclass 44.

8. Claim 51, in part, drawn to a method of treating a disease or disorder in a mammal comprising administering to the mammal or tissue a composition comprising the compound and an effective amount of a cationic delivery vehicle, made by mixing together a non-steroid drug, or modification or derivative thereof, a conjugating agent, and a polyamine, wherein the conjugating agent conjugates the polyamine to the steroid or modification or derivative thereof, purifying the conjugate, and mixing it with a lipid classified for example in class 514, subclass 44.

Claims 22-26 are generic to a plurality of patentably distinct inventions listed as inventions 1 and 2 above. Claims 27, 29, and 53 are generic to a plurality of patentably distinct inventions listed as inventions 3 and 4 above. Claims 31, 35-37, and 55 are generic to a plurality of patentably distinct inventions listed as inventions 5 and 6 above.

Claim 50 is generic to a plurality of patentably distinct inventions listed as inventions 7 and 8, above. Because steroids are biologically active compounds, they can be considered to be drugs, and so could be considered to be species of drugs. Claims will be examined to the extent that they are defined by the elected group.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1 and 2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions require the use of different compositions, i.e. a steroid or a non-steroid drug. The steroid moiety functions in the invention to facilitate crossing of a membrane and delivery to a cell nucleic by binding to a steroid receptor. The non-steroid-drug cannot function this way, so the inventions have different designs and effects. They are not disclosed as used together. Because invention 1 is unrelated to invention 2, it is also unrelated to inventions 4, 6, and 8, which require compositions with a non-steroidal drug. Similarly, invention 2 is unrelated to inventions 3, 5, and 7 because it requires a non-steroidal drug.

Inventions 1 and 3 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case it is routine in the art to mix pre-made cationic sterol derivatives, such as spermidine cholesterol carbamate, together with a colipid.

See e.g. Harris et al, US 5650096, claims 1-7. Further, in order to make the vehicle of invention 3, one need not follow the steps set forth in invention 1, wherein the steroid, conjugating reagent, and polyamine are all mixed together. Instead one could react the conjugating reagent separately with either the steroid or the polyamine elements, isolate the product, and subsequently mix it with the third element to form the claimed vehicle. Thus one could arrive at the claimed composition without performing the method steps set forth in group 1.

Inventions 1 and 5 are distinct because one is a method of making a product, and one is a method of using the product. As such, they are drawn to different processes with different outcomes, and are different statutory classes of invention. A similar relationship exists between inventions 1 and 7.

Inventions 2 and 4 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case one need not follow the steps set forth in invention 1, wherein the drug, conjugating reagent, and polyamine are all mixed together. Instead one could react the conjugating reagent separately with either the drug or the polyamine elements, isolate the product, and subsequently mix it with the third element to form the claimed vehicle. Thus one could arrive at the claimed composition without performing the method steps set forth in group 1.

Inventions 2 and 6 are distinct because one is a method of making a product, and one is a method of using the product. As such, they are drawn to different processes with different outcomes, and are different statutory classes of invention. A similar relationship exists between inventions 2 and 8.

Invention 3 is unrelated to inventions 4, 6, and 8. Invention 3 requires the use of a steroid, whereas inventions 4, 6, and 8 require a non-steroid drug. The steroid moiety functions in invention 3 to facilitate crossing of a membrane and delivery to a cell nucleic by binding to a steroid receptor. The non-steroid-drug cannot function this way, so the inventions have different designs and effects. They are not disclosed as used together. Similarly invention 4, which requires a non-steroid drug, is unrelated to the methods of inventions 5 and 7 which require a steroid. Inventions 5 and 7 are unrelated to inventions 6 and 8 for similar reasons.

Invention 3 is related to inventions 5 and 7 as a product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case invention 3 need not be used to deliver a compound to a cell or tissue, or to treat a disease or disorder, as required by inventions 5 and 7, respectively. Instead it could be used to deliver molecules to liposomes or across non-cell associated lipid bilayers.

Invention 4 is related to inventions 6 and 8 as a product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case invention 4 need not be used to deliver a compound to a cell or tissue, or to treat a disease or disorder, as required by inventions 6 and 8, respectively. Instead it could be used to deliver molecules to liposomes or across non-cell associated lipid bilayers.

Inventions 5 and 7 are related as methods of using a product to deliver a compound. Invention 5 requires delivery to a cell, and can be performed in vivo or in vitro. Invention 7 does not require delivery to a cell, and must be practiced in vivo. As a result the inventions, while overlapping, would require non-coextensive searches. Furthermore, invention 7 requires consideration of the enablement of treating a broad range of diseases or disorders (e.g. claim 50 lists 72 diseases or disorders for treatment). This represents a substantial examination burden. As a result examination of both inventions 5 and 7 represents a substantial search an examination burden and restriction between these inventions is justified.

Inventions 6 and 8 are related as methods of using a product to deliver a compound. Invention 6 requires delivery to a cell, and can be performed in vivo or in vitro. Invention 8 does not require delivery to a cell, and must be practiced in vivo. As a result the inventions, while overlapping, would require non-coextensive searches.

Furthermore, invention 8 requires consideration of the enablement of treating a broad range of diseases or disorders (e.g. the specification lists at least 72 diseases or disorders for treatment). This represents a substantial examination burden. As a result examination of both inventions 6 and 8 represents a substantial search an examination burden and restriction between these inventions is justified.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Peter Paras, can be reached at (571) 272-4517. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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